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PD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/828,143 03/24/97 HSIA

H 24400-101

HM12/0204

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EXAMINER

MARX, I

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

02/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/828,143**

Applicant(s)  
**Hsia**

Examiner  
**Irene Marx**

Group Art Unit  
**1651**



☒ Responsive to communication(s) filed on Nov 22, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 9-11 and 16-24 is/are pending in the application.

Of the above, claim(s) 9-11 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 16-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The amendment filed 11/22/99 is acknowledged. Claims 16-24 are being considered on the merits. Claims 9-11 are withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claim 23, presented in the amendment filed 8/6/99 regarding the amount of viable bacteria remaining "substantially constant for at least 6 months" for the compositions of claims 16, 17, 18, 19 or 20. The only composition tested is that of example 1, page 12, having specific, commercial grade, components. No fair indication or suggestion is found that "the amount of viable bacteria" in this specific composition or in an equivalent composition "remains substantially constant for at least 6 months".

No basis or support is found in the present specification for the recitation of "dry" weight in the claims. In the specification at page 9, lines 19-25 the percentage is based on the total mass of the mixture composition. No indication of dry or wet weight is found.

Therefore, this material raises the issue of new matter and should be deleted.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The presence of *Streptococcus* in the nutritional composition is queried, inasmuch as most strains in this genus are pathogenic. If specific species are intended, the claims should be amended accordingly.

Claim 23 is vague and indefinite in the recitation of "substantially constant", since the term "substantially" is ambiguous and open to interpretation, even when reading the claims in light of the specification. Is the amount of viable bacteria intended to remain 10%, 30%, 50%, 99%, and after how long, 1 year, 10 years, 100 years? See also the rejection regarding new matter.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levy (EP 430736) in light of Prescott *et al.*

The claims are drawn to a nutritional or dietary composition comprising solid dried viable bacteria, dried, non-living yeast and concentrated protein.

The cited reference discloses a nutritional or dietary composition comprising solid dried viable bacteria, dried, non-living yeast and concentrated protein, which appears to be identical to

the presently claimed strain (See, e.g., col. 2, lines 29-35). The viable *Bifidobacterium bifidus* bacteria constitute 10% of the composition, which is within the claimed range. In addition the composition comprises other lactic acid bacteria. Even though the brewer's yeast component is indicated at a higher percentage than claimed herein, and protein concentrate content is not explicitly disclosed, all of the limitations of the claimed composition appear to be met by the reference because brewer's yeast constitutes a concentrated source of protein. Prescott *et al.* adequately demonstrate that brewer's yeast is an art recognized source of concentrated protein. (See, e.g., bridging paragraph between pages 558-559). In addition, lactic acid bacteria are also a concentrated source of protein. Bacteria and yeasts biomass is art recognized as a concentrated source of protein, which is termed "single cell protein".

The referenced composition appears to be identical to the presently claimed nutritional composition and is considered to anticipate the claimed nutritional composition since it is apparent that it contains the same ingredients in substantially the same amounts. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy taken with Prescott *et al.*, Jolly, Friend and El-Megeed *et al.*.

Levy discloses a nutritional or dietary composition comprising solid dried viable bacteria, dried, non-living yeast and concentrated protein, which appears to be identical to the presently claimed composition (See, e.g., col. 2, lines 29-35). The viable *Bifidobacterium bifidus*

bacteria constitute 10% of the composition, which is within the claimed range. In addition the composition comprises other lactic acid bacteria. Even though the brewer's yeast component is indicated at a higher percentage than claimed herein, and protein concentrate content is not explicitly disclosed, brewer's yeast constitutes a concentrated source of protein. Prescott *et al.* adequately demonstrate that brewer's yeast is an art recognized source of concentrated protein. (See, e.g., bridging paragraph between pages 558-559). In addition, lactic acid bacteria are also a concentrated source of protein. Bacteria and yeasts biomass is art recognized as a concentrated source of protein, which is termed "single cell protein". One of ordinary skill in the art would presume that the composition comprising dried bacteria and yeast together stored as tablets as taught by Levy are in turn together stored in some sort of sealed, airtight container in the period after production and before consumption.

In addition Jolly and Friend disclose the advantageous combination of whey and soy proteins with bacteria and/or yeasts for nutritional purposes. See, e.g., Friend, page 128; Jolly, col. 3, lines 15-35. Note, in particular, the discussion throughout Friend regarding the numerous benefits of providing *Lactobacillus* biomass for nutritional and therapeutic purposes. Jolly is cited to demonstrate that bacteria, yeasts and soy beans are all excellent sources of protein. (See, e.g., col. 3).

The references may differ from the claimed invention in process parameters such as concentration of bacteria, of yeast and/or of protein, as well as in the specific types of protein used. However, the optimization of conditions identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art. The respective concentrations would have been adjusted by one of ordinary skill in the art depending on the particular application intended. See, e.g., ElMegeed *et al.* col. 11 for teachings regarding adjustments on the concentration of bacteria, yeast and/or protein.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Levy by adjusting the various parameters, such as the source and concentrations of bacteria, yeasts and protein, as suggested by

the teachings of the references, in order to maximize the benefits of consuming healthful sources of protein in combination with the other nutrients provided by microorganisms.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Applicants' arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicants argue the stability of the present composition. However, with respect to the amount of viable bacteria remaining "substantially constant for at least 6 months", as claimed in dependent claim 23, there is nothing on the record to provide basis or support for this claim, as noted in the rejection under 35 U.S.C § 112, regarding new matter. Applicants have demonstrated stability up to 18 months with a specific composition containing commercial grade components in specific amounts, wherein the viable bacteria are *Lactobacillus acidophilus*, the yeast is debittered brewer's yeast and the protein is soy protein isolate (Example 1, page 12).

As to the arguments that the yeast material is intended to provide nutrients for the *Lactobacillus*, applicants have not indicated when the nutrients are to intended be used by the solid, dried, viable *Lactobacillus*. The stable preparation shown in the specification at page 12, Example 1, contains a large amount of soy protein, and the amount of yeast is greater than the amount of *L. acidophilus*. There is no clear correlation between this example and the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Applicants have not demonstrated any unexpected properties of the composition as claimed.

No claim is allowed.

Serial No. 08/828143  
Art Unit 1651

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .



Irene Marx  
Primary Examiner  
Art Unit 1651